REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-6, 13-25, 27, 30 and 31 are pending. Claims 7-12, 26, 28, 29 and 32 were previously canceled and claims 1-6, 14, 20, 22 and 23 were canceled herein. Claims 13, 15-18, 27 and 31 have been amended herein.

The Amendments

Claim 13 was amended to incorporate certain subject matter of claim 14, which was canceled.

Claims 15-18 were amended to change their dependency to claim 13 since claim 14 was canceled.

Claims 27 and 31 were amended to change "and/or" to "and" in certain occurrences.

Rejection under 35 U.S.C. §102

Claims 1-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Avenia, *et al.* (U.S. Patent No. 4,041,076) (Avenia).

Without acquiescing in the arguments in the Office Action, Applicant submits that the cancellation of claims 1-6 above renders this ground of rejection moot.

Rejection under 35 U.S.C. §103

Claims 13-25, 27 and 30-31 were rejected under 35 U.S.C. §103(a) as unpatentable over Hui, *et al.* (EP 1,340,981 A2) (Hui) in view of Avenia.

Without acquiescing in the arguments in the Office Action, Applicant submits that the cancellation of claims 14, 20, 22 and 23 above renders this ground of rejection moot with respect to those claims.

The Office Action asserts that Hui discloses various competitive and noncompetitive methods/assays and a kit for detection and quantitative determination of amphetamine derivatives such as MDA, MDMA, MDEA, MDPA, BDB, and MBDB using antibody against amphetamine derivatives and label derivatives (such as fluorescent,

luminescent, radioactive isotope, etc.). Hui's amphetamine derivatives and immunogens, continues the Office Action, are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, recognizes the Office Action, the linking group or the position of linker at the amphetamine derivative is different from the present compound. The Office Action asserts further that Avenia discloses an amphetamine immunogen, labeled tracer and antibodies and discloses a competitive immunoassay method for detection of phenethylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia, contends the Office Action, is the same as the immunogen of present application. The Office Action concludes that it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia in the method of Hui with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

Claim 13 is directed to a method for determining a compound selected from the group consisting of 3,4-methylenedioxyamphetamine (MDA), 3,4-methylenedioxy-methamphetamine (MDMA), 3,4-methylenedioxyethylamphetamine (MDEA) and 4-hydroxy-3-methoxy-methamphetamine (HMMA). A sample suspected of containing the compound is combined with an antibody raised against the compound as designated in claim 13 and with a label conjugate of the formula set forth in the claim. Neither Hui nor Avenia disclose or suggest such a label conjugate. The disclosure of Avenia is directed to immunogens for preparing antibodies specific for certain amphetamine derivatives. To that end, Avenia prepares antigens by covalently linking a hapten of the formula indicated in the reference to a conventional immunogenic carrier. The patentee indicates that suitable proteins may be employed as the conventional immunogenic carrier such as gamma globulins and serum albumins of human and other animal origins.

There is no mention in Avenia of conjugates of labels and the haptens of the reference. There is no mention of conjugates of enzymes and the haptens of the reference. This is consistent with the teaching of Avenia, who is concerned with

conventional immunogenic carrier conjugates. The labeled derivative that Avenia employs in his assay is a radioactive amphetamine analog prepared by iodination with radioactive iodine of racemic 4-hydroxy-alpha-methylphenethylamine hydrobromide. Furthermore, Avenia goes on to state that his assays using the above reagents were superior in all cases to assays utilizing free radical labels and enzyme labels. Accordingly, Avenia does not disclose or suggest the label conjugates of claim 13, and, furthermore, it may be argued that Avenia teaches away from such conjugates. Therefore, the motivation for the skilled artisan to combine the teachings of Hui and Avenia is not sufficient.

Claims 15-18 depend ultimately from claim 13 and are, therefore, patentable over the combination of the teachings of Hui and Avenia by virtue of such dependency since claim 13 is patentable over Hui and Avenia as demonstrated above.

Claim 19 is patentable over the combined teachings of the references because Avenia and Hui do not disclose or suggest label conjugates as claimed. As mentioned above, Avenia arguably teaches away from labels other than radioactive labels and, furthermore, does not disclose or suggest radioactive label conjugates of the formula claimed in claim 19. Therefore, as mentioned above, the motivation for the skilled artisan to combine the teachings of Hui and Avenia is not sufficient.

Claims 21, 24 and 25 are patentable over the combined teachings of Hui and Avenia for reasons similar to those presented above with respect to the rejection of claim 13 over Hui and Avenia. There is no mention in Avenia of conjugates of labels, including enzyme labels, and the haptens of the reference. This is consistent with the teaching of Avenia, who is concerned with conventional immunogenic carrier conjugates. The labeled derivative that Avenia employs in his assay is a radioactive amphetamine analog prepared by iodination with radioactive iodine of racemic 4-hydroxy-alpha-methylphenethylamine hydrobromide. Furthermore, Avenia goes on to state that his assays using the above reagents were superior in all cases to assays utilizing free radical labels and enzyme labels. Accordingly, Avenia does not disclose or suggest the label conjugates of claim 13 and the reference, it may be argued, teaches away from such conjugates. The motivation for the skilled artisan to combine the teachings of Hui and Avenia is not sufficient.

Claim 27 is directed to a method for determining methylenedioxyamphetamine and/or methylenedioxymethamphetamine and/or methylenedioxyethamphetamine in a sample suspected of containing methylenedioxyamphetamine and/or methylenedioxymethamphetamine and/or methylenedioxyethamphetamine. A sample is combined in a medium with a conjugate of an enzyme and a methylenedioxyamphetamine analog and a conjugate of an enzyme and a methylenedioxymethamphetamine analog and a conjugate of an enzyme and a methylenedioxyethamphetamine analog, and with an antibody for methylenedioxyamphetamine raised against a compound of the formula as claimed, and an antibody for methylenedioxymethamphetamine raised against a compound of the formula as claimed, and an antibody for methylenedioxyethamphetamine raised against a compound of the formula as claimed. The medium is examined for the presence of a complex comprising the methylenedioxyamphetamine and the antibody for methylenedioxyamphetamine and a complex of the methylenedioxymethamphetamine and the antibody for methylenedioxymethamphetamine and a complex of the methylenedioxyethamphetamine and the antibody for methylenedioxyethamphetamine, the presence thereof indicating the presence of the methylenedioxyamphetamine and/or methylenedioxymethamphetamine and/or methylenedioxyethamphetamine in the sample.

The combination of Hui and Avenia does not disclose or suggest the method of claim 27 where the sample is combined with all three antibodies as claimed. Furthermore, as discussed above, there is no mention in Avenia of conjugates of labels, including enzyme labels, and the haptens of the reference. As discussed above, there is a lack of motivation for the skilled artisan to combine the teachings of Hui and Avenia in the manner in which the Office Action has done.

For reasons similar to those discussed above, the combined teachings of Hui and Avenia do not disclose or suggest the kits of claims 30 and 31.

Claims 13-25, 27 and 30-31 were rejected under 35 U.S.C. §103(a) as unpatentable over Rouhani, *et al.* (GB 2361473 A) (Rouhani) in view of Avenia.

Without acquiescing in the arguments in the Office Action, Applicant submits that the cancellation of claims 14, 20, 22 and 23 above renders this ground of rejection moot

with regard to those claims.

Furthermore, Applicant submits that claims 13, 15-19, 21, 24, 25, 27 and 30-31 are patentable over the combined teachings of Rouhani and Avenia for reasons similar to those set forth above with respect to the rejection of the above claims over the combined teachings of Hui and Avenia.

Conclusion

Applicant has demonstrated that Claims 13, 15-19, 21, 24, 25, 27, 30 and 31 satisfy the requirements of 35 U.S.C. §§102 and 103. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

Theodore J. Leitereg
Attorney for Applicant
Reg. No. 28,319

Theodore J. Leitereg
31420 Pennant Ct.
Temecula CA 92591
(602) 369-1751